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PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant of Kathleen C.M. Campbell

Art Unit 1614

Serial No. 10/694,432

Filed October 27, 2003

Confirmation No. 8934

For THERAPEUTIC USE OF D-METHIONINE TO REDUCE
THE TOXICITY OF RADIATION

Examiner Rebecca Cook

March 4, 2005

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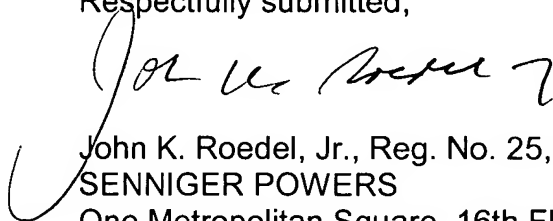
SIR:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

* In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicant submits the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein.

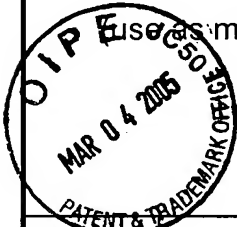
Applicant submits herewith copies of the prosecution history for the analogous grandparent and great-grandparent applications.

Respectfully submitted,


John K. Roedel, Jr., Reg. No. 25,914
SENNIGER POWERS
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102
(314) 231-5400

JKR/JSH/dep

PTO/SB/08A				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Use as many sheets as necessary)				Application Number	10/694,432
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				First Named Inventor	Kathleen C.M. Campbell
				Group Art Unit	1614
				Examiner Name	Rebecca Cook
Sheet	1	of	2	Attorney Docket No.	SIU 7399



OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	77	Claims as filed in grandparent application Serial No. 09/057,065 filed on April 8, 1998 (pages 59-64).	
	78	Office action, Paper #4 issued June 3, 1999 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	79	Response to Restriction and Election of Species filed July 6, 1999 in grandparent application Serial No. 09/057,065 filed on April 8, 1998 (page 1 only).	
	80	Office action, Paper #7 issued October 14, 1999 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	81	Amendment A filed February 14, 2000 in grandparent application Serial No. 09/057,065 filed on April 8, 1998 (page 1 only).	
	82	Office action, Paper #10 issued June 14, 2000 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	83	Amendment B After Final Rejection filed August 11, 2000 in grandparent application Serial No. 09/057,065 filed on April 8, 1998 (pages 1-4 only).	
	84	Advisory action, Paper #12 issued September 11, 2000 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	85	Notice of Allowance, Paper #15 issued February 16, 2001 in grandparent application Serial No. 09/057,065 filed on April 8, 1998.	
	86	Claims as filed in great-grandparent application Serial No. 08/942,845 filed on October 2, 1997 (pages 52-59).	
	87	Office action, Paper #4 issued May 29, 1998 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	

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	88	Response to Election of Species Requirement and Amendment A filed June 5, 1998 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (pages 1-2 only).	
	89	Office action, Paper #6 issued July 1, 1998 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	
	90	Amendment B, Response Under 37 C.F.R. 1.111 filed October 1, 1998 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (pages 1-2 only).	
	91	Office action, Paper #10, issued January 1, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	
	92	Amendment C filed March 8, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (page 1 only).	
	93	Office action, Paper #13, issued April 9, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	
	94	Preliminary Amendment filed July 6, 1999 in in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (pages 1-7 only).	
	95	Office action, Paper #17, issued August 6, 1999 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997.	
	96	Amendment D filed February 4, 2000 in great-grandparent application Serial No. 08/942,845, filed on October 2, 1997 (pages 1-6 only).	
	97	Notice of Allowance, Paper #21 issued May 3, 2000 in great-grandparent application Serial No. 08/942,845 filed on October 2, 1997.	

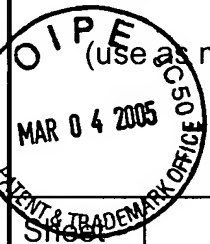
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			Group Art Unit	not yet assigned
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	1	2,732,400		Weiss	01-24-1956
	2	4,426,372		Borch	01-17-1984
	3	5,002,755		Mitchell et al.	03-26-1991
	4	5,292,773		Hirsch et al.	03-08-1994
	5	5,430,064		Hirsch et al.	07-04-1995
	6	5,466,678		Kawabata et al.	11-14-1995
	7	6,177,434		Kopke et al.	01-23-2001

FOREIGN PATENT DOCUMENTS

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		Office	Number ⁴	Kind Code ² (if known)			
	8	EP	06 200 04	A1	Fuji Kagaku Kogyo Kabushiki Kaisha	10-19-1994	

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	9	ALDEN, W. WESLEY et al., "Exacerbation of Cisplatin-Induced Nephrotoxicity by Methionine," <u>Chem.-Biol. Interactions</u> , 1984, 48, Pgs. 121-124		
	10	BASINGER, MARK A. et al., "Dithiocarbamate-Induced Biliary Platinum Excretion and the Control of cis-Platinum Nephrotoxicity," <u>Toxicology and Applied Pharmacology</u> , 1989, 97, Pgs. 279-288		
	11	BASINGER, MARK A. et al., "L-Methionine Antagonism of cis-Platinum Nephrotoxicity," <u>Toxicology and Applied Pharmacology</u> , 1990, 108, Pgs. 1-15		
	12	BASINGER, MARK A. et al., "L-Methionine Suppresses Pathological Sequelae of cis-Platinum in the Rat," <u>Fundamental and Applied Toxicology</u> , 1990, 14, Pgs. 568-577		
	13	BOOGAARD, PIETER J. et al., "4-Methylthiobenzoic Acid Reduces Cisplatin Nephrotoxicity In Rats Without Compromising Anti-Tumor Activity," <u>Biochemical Pharmacology</u> , 1991, Vol. 41, No. 12, Pgs. 1997-2003		
	14	BOOGAARD, PIETER J. et al., "The Role of Methallothionein in the Reduction of Cisplatin-Induced Nephrotoxicity by Bi ³⁺ -Pretreatment in the Rat <i>In Vivo</i> and <i>In Vitro</i> , Are Antioxidant Properties of Methallothionein More Relevant than Platinum Binding?", <u>Biochemical Pharmacology</u> , 1991, Vol. 41, No. 3, Pgs. 369-375		
	15	BURCHENAL, JOSEPH H. et al., "Studies of Cross-Resistance, Synergistic Combinations and Blocking of Activity of Platinum Derivates," <u>Biochimie</u> , 1978, 60, No. 9, Pgs. 961-965		
	16	CAMPBELL, KATHLEEN C.M. et al., "A Review of Cisplatin Protective Agents Emphasizing Nephro- and Otoprotectants," <u>Proposed Review Article Not Yet Submitted for Publication, Including Additional Reference Lists</u>		
	17	CAMPBELL, KATHLEEN C.M. et al., "D-Methionine Provides Excellent Protection from Cisplatin Ototoxicity in the Rat," <u>Hearing Research</u> , 1996, 102, Pgs. 90-98		

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	18	CAMPBELL, KATHLEEN C.M. et al., "D-Methionine Provides Protection Against Cisplatin Damage the Rat Stria Vascularis: A Semi-Quantitative Analysis," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 537, Pgs. 135	
	19	CARDINI, G. et al., "La Radioprotezione Dei Cromosomi Delle Cellule Midollari Umane In Vitro," <u>Radiobiologia Radioterapia E Fisica Medica</u> , 1967, Vol. 22, No. 6, Pgs. 371-375	
	20	CARRITHERS, S. L. et al., "Methylation Of Radiation Protector Compounds By Thiol Methyltransferase," <u>FASEB</u> , 1991, Vol. 5, No. 4, Pg. A824	
	21	CHURCH, MICHAEL W. et al., "The Comparative Effects of Sodium Thiosulfate, Diethyldithiocarbamate, Fosfomycin and WR-2721 on Ameliorating Cisplatin-Induced Ototoxicity," <u>Hearing Research</u> , 1995, 86/1,2, Pgs. 195-203	
	22	CORREA, J. N. et al., "Radiosensitization and radioprotection on murine chondrosarcoma," <u>Radiation Research</u> , 1978, Vol. 74, No. 3, Pg. 517	
	23	DE VECCHI, A., "Sperimentazione Clinica Di Una Nuova Sostanza Radioprotettiva (Cloruro Di Metil-Metionin-Sulfonio)," <u>Radiobiologia Radioterapia E Fisica Medica</u> , 1967, Vol. 22, No. 5, Pgs. 355-370	
	24	DEDON, PETER C. et al., "Characterization of the Reactions of Platinum Antitumor Agents with Biologic and Nonbiologic Sulfur-Containing Nucleophiles," <u>Biochemical Pharmacology</u> , 1987, Vol. 36, No. 12, Pgs. 1955-1964	
	25	DEEGAN, PATRICIA M. et al., "The nephrotoxicity, cytotoxicity and renal handling of a cisplatin-methionine complex in male Wistar rats," <u>Toxicology</u> , 1994, 89, Pgs. 1-14	
	26	DREWINKO, B. et al., "The Effect of <i>cis</i> -Diamminedichloroplatinum(II) on Cultured Human Lymphoma Cells and Its Therapeutic Implications," <u>Cancer Research</u> , December 1973, 33, Pgs. 3091-3095	
	27	DROBNIK, JAROSLAV et al., "Inactivation Of Bacteriophages With <i>Cis</i> -Platinum(II) Diamminedichloride," <u>Chem.-Biol. Interactions</u> , 1975, Pgs. 365-375	
	28	FRIEDMAN, M. E. et al., "The Blocking Of The Tetrachloroplatinate(II) Inhibition Of Malate Dehydrogenase By Sulfur-Containing Amino Acids," <u>Biochimica et Biophysica Acta</u> , 1974, 341, Pgs. 277-283	

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	29	FRIEDMAN, MENDEL et al., "The Utilization and Safety of Isomeric Sulfur-Containing Amino Acids in Mice," <u>J. Nutr.</u> , 1984, 114, Pgs. 2301-2310	
	30	GABAZADEH, RAMIN et al., "Protection of Both Auditory Hair Cells and Auditory Neurons from Cisplatin Induced Damage," <u>Acta Otolaryngol</u> (Stockholm), 1997, 117, Pgs. 232-238	
	31	GANDARA, DAVID R. et al., "Cisplatin Chemoprotection and Rescue: Pharmacologic Modulation of Toxicity," <u>Seminars in Oncology</u> , February 1991, Vol. 18, No. 1, Suppl. 3, Pgs. 49-55	
	32	GANDARA, DAVID R. et al., "Evaluation of Cisplatin Dose Intensity: Current Status and Future Prospects," <u>Anticancer Research</u> , 1989, 9, Pgs. 1121-1128	
	33	GESSLER, N. et al., "Antiradiation effects of S-methylmethionine (Vitamin U)," <u>Prikl. Biokhim. Mikrobiol.</u> , 1996, Vol. 32, No. 6, Pgs. 666-668	
	34	GLOVER, DONNA et al., "Clinical Trials of WR-2721 and Cis-Platinum," <u>I. J. Radiation Oncology, Biology, Physics</u> , May 1989, Vol. 16, No. 5, Pgs. 1201-1204	
	35	HANNERMANN, JORG et al., "Cisplatin-Induced Lipid Peroxidation and Decrease of Gluconeogenesis in Rat Kidney Cortex: Different Effects of Antioxidants and Radical Scavengers," <u>Toxicology</u> , 1988, 51, Pgs. 119-132	
	36	HAYES, D. et al., "Amelioration Of Renal Toxicity Of High Dose Cis-Platinum Diammine Dichloride (CPDD) By Mannitol Induced Diuresis," <u>Proc. Am. Assoc. Cancer Res.</u> , 1976	
	37	INFANTE, G. A. et al., "Chemical radioprotection on biological important compounds," <u>Radiation Research</u> , 1976, Vol. 67, No. 3, Pg. 637	
	38	JONES, MARK M. et al., "Coadministration of Dimethyl Sulfoxide Reduces Cisplatin Nephrotoxicity," <u>Anticancer Research</u> , 1991, 11, Pgs. 1939-1942	
	39	JONES, MARK M. et al., "Control of Nephrotoxicity in the Rat during Repeated cis-Platinum Treatments," <u>Journal of Applied Toxicology</u> , 1989, Vol. 9(4), Pgs. 229-233	
	40	JONES, MARK M. et al., "Control of the Nephrotoxicity of Cisplatin by Clinically Used Sulfur-Containing Compounds," <u>Fundamental and Applied Toxicology</u> , 1992, 18, Pgs. 181-188	
	41	JONES, MARK M. et al., "Inhibition of cis-diamminedichloroplatinum (II)-induced renal toxicity in the rat," <u>Cancer Chemotherapy and Pharmacology</u> , 1986, 17, Pgs. 38-42	

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	42	JONES, MARK M. et al., "Relative effectiveness of some compounds for the control of cisplatin-induced nephrotoxicity," <u>Toxicology</u> , 1991, 68: Pgs. 227-247	
	43	JONES, MARK M. et al., "Thioether Suppression of Cisplatin Nephrotoxicity in the Rat," <u>Anticancer Research</u> , 1991, 11, Pgs. 449-454	
	44	JONES, MARK M. et al., "Thiol and Thioether Suppression of Cis-Platinum-Induced Nephrotoxicity in Rats Bearing the Walker 256 Carcinosarcoma," <u>Anticancer Research</u> , 1989, 9: 1937-1942	
	45	KIDO, K., "The influence of methylmethionine sulfonium chloride (MMSC) on survivors of mice after X-ray irradiation, especially the consideration of the drug effect for the degeneration of intestinal mucosa," <u>Kansai Ika Daigaku Zasshi</u> , 1973, Vol. 25, No. 1, Pgs. 104-107	
	46	KIES, CONSTANCE et al., "Comparative Value of L-, DL-, and D-Methionine Supplementation of an Oat-based Diet for Humans," <u>J. Nutr.</u> , 1975, 105, Pgs. 809-814	
	47	KOPKE, RICHARD D. et al., "Use of Organotypic Cultures of Corti's Organ to Study the Protective Effects of Antioxidant Molecules on Cisplatin-Induced Damage of Auditory Hair Cells," <u>The American Journal of Otolaryngology</u> , 1997, 18, 559-571	
	48	KORVER, K. D. et al., "Round window application of D-methionine provides cisplatin otoprotection," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 536, Pg. 135	
	49	KOVACS, V. et al., "Study of the Radiation Protection Effect of Selenium-Methionine by Determining the Paramagnetic Properties of Liver Tissues of Mice," 1988, <u>Acta Physica Hungarica</u> , Vol. 64, No. 1-3, Pgs. 321-326	
	50	MEKHTIEV, M. A. et al., "Radioprotective effect during the separate and combined use of DL-methionine and thyroxine," <u>Database Chemabs Chemical Abstracts Service</u> , Abstract No. 76:54431, 1970 (see also <i>Tr. Inst. Fiziol., Akad. Nauk Azerb. SSR</i> , Vol. 11, pp. 83-100, 1970)	
	51	MELVIK, JAN EGIL et al., "Reduction of cis-Dichlorodiammineplatinum-Induced Cell Inactivation by Methionine," <u>Inorganica Chimica Acta</u> , 1987, 137, Pgs. 115-118	
	52	MERRIN, CLAUDE, "A New Method To Prevent Toxicity With High Doses Of Cis Diammine Platinum (Therapeutic Efficacy In Previously Treated Widespread And Recurrent Testicular Tumors)," <u>Proc. Am. Assoc. Cancer Res.</u> , 1976	

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				Application Number	10/694,432
				Filing Date	October 27, 2003
				Confirmation Number	not yet assigned
				First Named Inventor	Campbell
				Group Art Unit	not yet assigned
Sheet	6	of	8	Attorney Docket No.	SIU 7399

	53	MOLTENI, F. et al., "The use of S-adenosyl-methionine as a radioprotective agent," <u>Gazetta Medica Italiana</u> , 1978, Vol. 137, No. 7-8, Pgs 303-308	
	54	MONTINE, THOMAS J. et al., "Role of Endogenous Sulfur-Containing Nucleophiles in an In Vitro Model of cis-Diamminedichloroplatinum(II)-Induced Nephrotoxicity," <u>Biochemical Pharmacology</u> , 1990, Vol. 39, No. 11, Pgs. 1751-1757	
	55	NAKANO, SACHIKO et al., "Potentiation of Cisplatin-Induced Lipid Peroxidation in Kidney Cortical Slices by Glutathione Depletion," <u>Japan. J. Pharmacol.</u> , 1989, 50, Pgs. 87-92	
	56	ORMOND, T. et al., "Reduced Nephrotoxicity <u>In Vivo</u> and <u>In Vitro</u> of Cisplatin-Methionine Complex," <u>Brit. J. Pharmacol.</u> (suppl)., 1988, 95, Pg. 584P	
	57	PRINTEN, KENNETH J. et al., "Utilization of D-methionine during total parenteral nutrition in postsurgical patients," <u>The American Journal of Clinical Nutrition</u> , June 1979, 32, Pgs. 1200-1205	
	58	RAVI, RADHIKA P. et al., "Relationship of Pharmacodynamic Effects of Cisplatin to the Glutathione Levels in Cochlea, Inferior Colliculus and Kidney," <u>Pharmacologist</u> , 1991, 33(3), D-19, 402, P. 217	
	59	RAVI, RADHIKA P. et al., "Diethyldithiocarbamate Protects Against Cisplatin Ototoxicity and Nephrotoxicity," <u>Otolaryngology Head and Neck Surgery</u> , 1992, 107(2), Poster 5, P. 232	
	60	RESER, D. H. et al., "Physiological evidence for protection from cis-platin ototoxicity by D- and L-methionine in vivo," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 203, P. 51	
	61	RHO, M. B. et al., "Structural evidence for protection from cisplatin ototoxicity by both D- and L-methionine in vivo," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 202, P. 51	
	62	ROMITO, S., "Sulla radioprotezione cromosomica in vitro: esperienze con metionina, acido aspartico, leucina, lisina," <u>Fracastoro</u> , 1969, Vol. 62, No. 6, Pgs. 576-581	
	63	SALIKHODZHAEV, Z. et al., "Stimulation of postirradiation recovery of rat haemopoiesis by a cobalt preparation," <u>Database Biosis Biosciences Information Service</u> , Philadelphia, Pennsylvania, Abstract No. 08095385 (see also <u>Radiobiologia</u> , Vol. 31, No. 6, pp. 835-837, 1991)	
	64	SCHEIN, P. S., "Ethyol™ (WR-2721): a chemoprotective agent for platinum anti-cancer drugs," <u>Speaker Abstracts</u> (XP-002053095)	

Examiner Signature	Date Considered
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	65	SCHWEITZER, VANESSA GAYL, "Cisplatin-Induced Ototoxicity: The Effect of Pigmentation and Inhibitory Agents," <u>Laryngoscope</u> , April 1993, 103, Pgs. 1-52	
	66	SHA et al., "Antioxidant therapy attenuates gentamicin-induced ototoxicity," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 535, P. 134	
	67	SPEER, R. J. et al., "Coordination Complexes of Platinum as Antitumor Agents," <u>Cancer Chemotherapy Reports</u> , 1975, Part I, Vol. 59, No. 3, Pgs. 629-641	
	68	SRINIVASAN, V. et al., "Radioprotection By Misoprostol (PGE ₁ Methyl Analog) In Combination With Vitamin E, Selenomethionine and WR-3689794," <u>Eicosanoids and Other Bioactive Lipids in Cancer, Inflammation, and Radiation Injury 2</u> , edited by K. V. Honn et al., 1997, Plenum Press, New York, Pgs. 791-797	
	69	TOGNELLA, SERGIO, "Pharmacological interventions to reduce platinum-induced toxicity," <u>Cancer Treatment Reviews</u> , 1990, 17, Pgs. 139-142	
	70	TRESKES, MARCO et al., "WR2721 as a modulator of cisplatin- and carboplatin-induced side effects in comparison with other chemoprotective agents: a molecular approach," <u>Cancer Chemotherapy and Pharmacology</u> , 1993, 33, Pgs. 93-106	
	71	VAN DE WATER, T. et al., "Oxidative stress in the inner ear: Combinatorial therapy;" (202) M. B. Rho et al., "Structural evidence for protection from cisplatin ototoxicity by both D- and L-methionine in vivo," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 6, P. 2	
	72	WALKER, ERNEST M., JR. et al., "Methods of Reduction of Cisplatin Nephrotoxicity," <u>Annals of Clinical and Laboratory Science</u> , 1981, Vol. 11, No. 5, Pgs. 397-409	
	73	WARD, J. M. et al., "Modification of the Renal Toxicity of <i>cis</i> -Dichlorodiammineplatinum(II) With Furosemide in Male F344 Rats," <u>Cancer Treatment Reports</u> , 1977, Vol. 61, No. 3, Pgs. 375-379	
	74	WHITWORTH, C. A. et al., "Alpha-lipoic acid as a protective agent against ototoxicity;" (535) S. H. Sha et al., "Antioxidant therapy attenuates gentamicin-induced ototoxicity," <u>Abstracts of the Twenty-First Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology</u> , February 15-19, 1998, Abstract No. 532, P. 134	

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	75	ZEZULKA, ALLISON YATES et al., "Nitrogen Retention in Men Fed Isolated Soybean Protein Supplemented with L-Methionine, D-Methionine, N-Acetyl-L-Methionine, or Inorganic Sulfate," <u>J. Nutr.</u> , 1976, 106, Pgs. 1286-1291	
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